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09/465,667	12/17/1999	LENNART CEDGARD	ALBIHN-W-3.3	9154

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ALBIHNS STOCKHOLM AB
BOX 5581, Linnegatan 2
SE-114 85 STOCKHOLM; Sweden
STOCKHOLM,
SWEDEN

EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/465,667	CEDGARD, LENNART	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,14-27 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *22-27 and 29-32* is/are allowed.

6)☐ Claim(s) *11,12 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 11, 12, 14-27 and 29-32 {as filed 10/20/2003} are pending and under examination.

Claims 1-10 were canceled by applicant in Preliminary amendment [paper No. 8 filed 2/05/2001]. Claim 13 was canceled by applicant [Paper No. 11 filed 5/21/2001]. Claim 28 was canceled by applicant [Paper No. 20 filed 8/07/2002].

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 12 and 14-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,396,631 taken with US 5,536,526; US 5,531,989; US 5,422,346; US 4,021, 545 and US 4,806,368

The claims are directed to a method for producing tablets with live bacteria comprising step of mixing live bacteria with fructose oligosaccharide or inulin and step of compressing the mixture into tablets. The final compressed tablet is characterized by good friability within 0.1-1.0 and by bacterial viability after compressing tablets of about 60%. Some claims are/are further drawn to the use of particular species of lactic bacteria in the method for producing tablets with live bacteria. Some claims are further drawn to the use of fructose oligosaccharide or inulin at concentration 40-99.5% in the tablet in the method for producing tablets with live bacteria. Some claims are further drawn to incorporation of additives into the tablet including starch or calcium diphosphate in the method for producing tablets with live bacteria.

US 4,396,631 teaches a method for producing hard tablets with live bacteria wherein the method comprises step of mixing live bacteria with binding materials and additives including starch, sugar, gelatin and others additives suitable for forming tablets and step of compressing the mixture in order to form tablets with viable bacteria. The cited patent clearly discloses that bacteria retain high viability ($2x10^8$ cfu) after formation of the compressed tablets as well as during storage of the compressed tablets (col. 4, example 1).

The cited patent US 4,396,631 is silent with regard to friability of tablets. However, it is well established in the art that compressed tablets have friability of about 0.3 according to good manufacturing practice as demonstrated by US 5,536,526 (col. 4, lines 7-10).

The cited patent US 4,396,631 is lacking the disclosure about the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria.

However, US 5,422,346 teaches the use of fructose oligosaccharide or inulin in the method for producing hard tablets and it also teaches that inulin is compressed into tablets without the need of additional binding materials such as starch, for example: col. 8, lines 41-44. The cited patent US 5,422,346 also teaches that inulin is a suitable substrate for promoting growth of beneficial bacteria such as lactic bacteria including *Bifidobacterium sp* and that the pathogenic enteric bacteria cannot utilize inulin, unlike the beneficial bacteria in the gastrointestinal tract of animals (col. 18, lines 25-37).

US 5,531,989 is relied upon to demonstrate a method for producing dry agglomerates with live lactic bacteria by using fructose oligosaccharide or inulin wherein the final products comprise about 40-60 % by weight of inulin and/or fructose oligosaccharide and about 0.1-20% by weight of live lactic bacteria of *Lactobacillus sp.* and /or *Bifidobacterium sp.* (col. 13, lines

38-50 and col. 4, lines 1-30). Although the cited patent US 5,531,989 is silent about hardness and/or friability of the final agglomerated products, it clearly teaches the use of live lactic bacteria in combination with inulin in the method of producing agglomerates wherein the final agglomerated products contain viable bacteria.

In addition, US 4,021, 545 is relied upon for the disclosure about the use of various materials including inulin, starch, calcium diphosphate and others in the methods for producing hard tablets (col. 5, example 4).

And US 4,806,368 is relied upon for the disclosure about the use of various materials including vitamins, cellulose or fibers in the methods for producing hard tablets (col. 5, example 4). The cited US 4,806,368 also teaches that hard tablets allow for prolonged storage of live bacteria containing tablets when compared to the dry agglomerated powders.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin for starch or to add inulin into the tablets in the method for making hard tablets with viable bacteria in the method of US 4,396,631 with a reasonable expectation in success for producing hard tablets with viable bacteria because inulin has been taught as a substitution for the other binding agents including starch in the hard tablets {US 5,422,346; US 4,021,545} and because inulin has been demonstrated in the products with live bacteria {US 5,531,989} as adequately demonstrated by the cited prior art. One ordinary of skill in the art would have been motivated to incorporate inulin in the live bacteria-containing products including tablets for the expected gastrointestinal health benefits upon administration because inulin is a beneficial substrate for promoting growth of beneficial probiotic bacteria including lactic bacteria and because inulin is not readily utilized by pathogenic enteric bacteria

{US 5,422,346}. Thus, incorporation of inulin in the live-bacteria-containing products including tablets provides for the effects of the competitive exclusion of pathogenic bacteria by beneficial probiotic bacterial preparations {US 5,422,346; US 5,531,989}. One ordinary of skill in the art would also have been motivated to make hard tablets with live lactic bacteria because the hard tablets allow for preservation of the viability of live lactic bacteria for longer periods of storage unlike the dry bacterial powders as adequately taught by the prior art {US 4,806,368}. Accordingly, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Declaration by Dr. Henning Kristensen filed 4/07/2004 and arguments based thereon have been fully considered.

However, some of the results or effects disclosed in the declaration are confusing as to the significance of the differences in productivity indicated. One of the arguments is drawn to the use of "a lower punching pressure" for making tablets with live bacteria (page 3, it.18). Yet, the claimed method is not so limited. Furthermore, the claimed ranges of tablet hardness fall within the ranges that are established as good manufacturing practices as discussed above. Therefore, the punching pressure that has been used to achieve the tablet hardness as required by the claimed invention is within that is established as good manufacturing practice or that is used in the prior art. The other argument, as drawn to 200% increase in bacterial viability (page 4, it. 18), is not considered persuasive in the lack of evidence or data associated with this effect as argued.

The instant specification discloses 60% increase in viability for a mixture of particular species of lactic bacteria in hard tablets as result of substitution of inulin for starch. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim. Thus, claims 22-27 and 29-32 are free from prior art.

In response to the argument that the examiner has combined an excessive number of references up to 6 (page 4, it. 21), it is noted that reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Vera Afremova

AU 1651

June 17, 2004

VERA AFREMOVA

PATENT EXAMINER